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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/004,562	12/05/2001	Tony Fleming	1440.1088-005	8389

7590 10/06/2004

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EXAMINER	
BASI, NIRMAL SINGH	
ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 10/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/004,562	FLEMING ET AL.	
	Examiner	Art Unit	
	Nirmal S. Basi	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 May 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *8,9,12,13 and 16-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) *8-9, 12-13, 16-38* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. ***Election/Restriction***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 8-9 and 21-26, drawn to method of treating an allergic or inflammatory condition associated with IgE-mediated degranulation by administering an agent that binds to CD81 and inhibits IgE-mediated degranulation, class 514, subclass 2.

II. Claims 12-13 and 27, drawn to method of inducing an inflammatory comprising administering an effective amount of an agent that binds CD81 and induces IgE-mediated degranulation, class and subclass can not be defined because no agent has been disclosed.

III. Claims 16 and 28-29, 35, drawn to assay for identifying agents which alter CD81-mediated signal transduction, class 435, subclass 7.21.

IV. Claims 17, 30-34 and 36 drawn to assay for identifying agents which alter CD81-mediated regulation of cell surface receptor signal transduction, class 435, subclass 7.21.

V Claims 19-20 and 38, drawn method of inhibiting passive cutaneous anaphylaxis in a mammal by administering an agent /antibody which induces CD81-mediated signal transduction, class 514, subclass 2.

VI. Claims 37, drawn an vivo assay for identifying an agent that inhibits mass cell activation comprising injecting antigen specific IgE intradermally, class 436, subclass 513.

The inventions are distinct, each from the other because of the following reasons:

Inventions I- VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The instant specification does not disclose that these methods would be used together. The method of Groups I-VI are all unrelated as they comprise distinct steps and utilize different products which demonstrates that each method has a different mode of operation. Each invention performs this function using a structurally and functionally divergent material. The methodology and materials necessary for treating an allergic or inflammatory condition associated with IgE-mediated degranulation (Group I) differ significantly for each of the other Groups. Group I treats an inflammatory response. The methodology and materials necessary for inducing an inflammatory (Group II) differ significantly for each of the other Groups. Group II induces an inflammatory response. The methodology and materials necessary identifying agents which alter CD81-mediated signal transduction (Group III) differ significantly for each of the other Groups. Group III measures CD81-mediated signal transduction. The methodology and materials necessary for identifying agents which alter CD81-mediated regulation of cell surface receptor signal transduction (Group IV) differ significantly for each of the other Groups. Group IV measures cell surface receptor signaling. Group III does not require

the cell surface receptor of Group IV. The methodology and materials necessary for inhibiting passive cutaneous anaphylaxis in a mammal by administering an agent /antibody which induces CD81-mediated signal transduction (Group V) differ significantly for each of the other Groups. The methodology and materials necessary for identifying an agent that inhibits mass cell activation (Group VI) require injecting antigen specific IgE intradermally and therefore differ significantly for each of the other Groups. Therefore, each method is divergent in materials and steps. For these reasons the Inventions I-VI are patentably distinct.

Furthermore, the distinct steps and products require separate and distinct searches. The inventions of Groups I-VI have a separate status in the art as shown by their different classifications. It would be burdensome to search the inventions of Groups I-VI together. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

2. This application contains claims directed to the following patentably distinct species of the claimed invention: wherein the allergic or inflammatory condition is selected from the group consisting of autoimmune (Type 1) diabetes mellitus, rheumatoid arthritis, ankylosing spondylitis, sarcoidis, Sjögren's syndrome, multiple sclerosis, inflammatory bowel disease, dermatomyositis, scleroderma, polymyositis, systemic lupus erthematosus, biliary cirrhosis, autoimmune thyroiditis, auto immune hepatitis, psoriasis, contact sensitivity and atopic dermatatitis.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 23 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nirmal S. Basi whose telephone number is 571-272-0868. The examiner can normally be reached on 9:00 AM-5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda G Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Nirmal S. Basi
Art Unit 1646
September 29, 2004

BRENDA BRUMBACK
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600